2013 discharge: European Medicines Agency (EMA)

2014/2102(DEC) - 29/04/2015 - Text adopted by Parliament, single reading

The European Parliament adopted by 556 votes to 110, with 26 abstentions, a decision to grant discharge to the Executive Director of the European Medicines Agency (EMA) for the financial year 2013. The vote on the discharge decision approved the closure of the accounts (in accordance with Annex VI, Article 5(1) of the Rules of Procedure of the European Parliament.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Authority for the financial year 2013 are reliable, and that the underlying transactions are legal and regular, Parliament adopted by 570 votes to 81, with 29 abstentions, a resolution containing a number of recommendations that form an integral part of the discharge decision and as well as the general recommendations that appear in the resolution on performance, financial management and control of EU agencies:

- **Centre's financial statements**: Parliament noted that the final budget of the Centre for the financial year 2013 was EUR 251.56 million, representing an increase of 13.07% compared to 2012. The overall contribution of the Union to the Centre's budget for 2013 amounted to EUR 40 937 951.
- **Commitments and carry-overs**: Parliament noted that budget monitoring efforts during the financial year 2013 resulted in a relatively low budget implementation rate of 96.76% and that the payment appropriations execution rate was 83.49%. It noted the Agency's compliance with the principle of annuality and the timely execution of its budget.

Parliament also made a series of observations on transfers, procurement and recruitment procedures, internal controls and internal audits and the prevention and management of conflicts of interest. It acknowledged from the Agency that the transparency criteria for partner, patient, healthcare and consumer organisations had been revised during 2014 in order to increase the transparency of funding.

Transparency and data confidentiality: Parliament regrets that the policies on proactive publication of clinical trial data recently adopted by the Agency **go against the transparency provisions** of Regulation (EU) No 536/2014 of the European Parliament and the Council1 (the Clinical Trials Regulation) by allowing companies to redact data based on potential jeopardy of commercial interests. It notes with regret that the Agency's understanding of what constitutes commercial confidential information (CCI) is far too broad and includes companies to redact key data about the trial design, methods. It called on the Agency to properly implement the provisions of the Clinical Trials Regulation especially with regard to clinical trial data not to be considered CCI.

Parliament also called on the Agency to publish on its website detailed reports of **the scientific advice provided by the Agency to pharmaceutical companies during the drug development and pre-registration process** at the time of trial authorisation and in any case not later than 12 months after the end of the trial.

Lastly, it noted that advice provided by regulators to companies on drug development and pre-registration plans cannot be considered CCI since there is an overriding public interest in disclosure.